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Bayer HealthCare Pharmaceuticals



Paul R. Berry Vice President, General Counsel and Secretary Law & Patents

April 30, 2004

Nicole C. Hall, Esq.
Senior Counsel
Office of Counsel to the Inspector General
Specification Procedure
U.S. Department of Health & Human Services
Cohen Building, Room 5527
330 Independence Ave., S.W.
Washington, D.C. 20201

Mr. Joseph Palermo First DataBank Inc. 111 Bayhill Drive San Bruno, CA 94066

Re: Report of Average Sale Price - 1st Quarter 2004

In conformance with: (a) the terms of the Corporate Integrity Agreement (the "CIA") entered into January 23, 2001 between Bayer Corporation ("Bayer") and the Office of the Inspector General of the United States Department of Health and Human Services ("OIG"); and (b) the State Settlement Agreement entered into August 6, 2001 among Bayer Corporation ("Bayer") and the forty-five states, plus the District of Columbia, specified on attachment hereto, Bayer submits the following:

- Report of Average Sale Price for the first quarter 2004 (Section III(D)(2)(b)). This information is also included on the enclosed diskette.
- A detailed description of the methodology used to calculate the Average Sale Price (Section III (D)(2)(c)) certified by a high managerial agent of Bayer Pharmaceuticals Corporation and the Biological Products Division of Bayer HealthCare, LLC.

We wish to stress that this report of Average Sale Price arises from the above-referenced settlement. It is not intended to set reimbursement rates and is not a substitute for the reporting of Average Wholesale Price (AWP), Average Manufacturers Price (AMP) and/or Best Price (BP).

Bayer Pharmaceuticals Corporation 400 Morgan Lane West Haven, CT 06516

Phone: 203 812-6081 Fax: 203 812-2795 paul.berry.b@bayer.com

^{1 &}quot;On January 1, 2003, Bayer Corporation was reorganized. The business, assets and operations of the unincorporated division of Bayer Corporation known as Bayer Pharmaceuticals became a stand alone business operated through Bayer Pharmaceuticals Corporation, a Delaware corporation, a newly formed subsidiary of Bayer Corporation. The business, assets and operations of the unincorporated division of Bayer Corporation known as Bayer Biological Products became a stand alone business operated through Bayer HealthCare LLC, a Delaware limited liability company, a newly formed subsidiary of Bayer Corporation."

Page 2 April 30, 2004

Please contact Mr. Jeffrey Greenman (203-812-2037) or me (203-812-6081) if you have any questions.

Very truly yours,

Paul R. Berry

ер

Enclosures

cc: Attached List

CERTIFICATION

The undersigned, a high managerial agent of Bayer Pharmaceuticals Corporation and the Biological Products Division of Bayer HealthCare, LLC, hereby certifies that the attached Average Sale Price information has been communicated to First DataBank and to the State Medicaid programs listed on the attached and that it has been calculated in accordance with the methodology described herein. I further acknowledge that the Average Sale Prices so reported will be filed with the State Medicaid programs identified below.

State Medicaid Programs:

Per attached list.

Jeffrey M. Greenman Compliance Officer

certification_1st quarter 2004

Case 1:01-cv-12257-PBS Document 3740-3 Filed 02/08/07 Page 6 of 20

Pharmacy Director
Alabama Medicaid Agency
501 Dexter Avenue
Montgomery, Alabama 36104

Roberto Martinez, Chief Medical Policy Division 714 P Street Room 1216 Sacramento, California 95814

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Hoover State Office Building
Division of Medical Services
Des Moines, Iowa 50319

Pharmacy Director Bureau of Health Services Financing 6080 Esplanade Avenue Baton Rouge, Louisiana 70806

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Oklahoma City, Oklahoma 73105

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Pharmacy Director Division of Health Care Financing 2300 Capital Avenue 154 Hathaway Building Cheyenne, Wyoming 82002

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April 28, 2005

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Senior Counsel
Office of Counsel to the
Inspector General
Specification Procedure
U.S. Department of Health &
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Salt Lake City, Utah 84101

Robert J. Hawley, Esq. The Hearst Corporation Office of General Counsel 959 Eighth Avenue New York, New York 10019

Enyor Phermocenticals Conforetion 400 Morgan Lane West Haven, CT 06516

Phone: 203 812-6081 Fax: 203 812-2795 paul.berry.b@bayer.com

Re: Report of Average Sale Price – 1st Quarter 2005

In conformance with: (a) the terms of the Corporate Integrity Agreement (the "CIA") entered into January 23, 2001 between Bayer Corporation ("Bayer") and the Office of the Inspector General of the United States Department of Health and Human Services ("OIG"); and (b) the State Settlement Agreement entered into August 6, 2001 among Bayer Corporation ("Bayer") and the forty-five states, plus the District of Columbia, specified on attachment hereto, Bayer submits the following:

1. Report of Average Sale Price for the first quarter 2005 (Section III(D)(2)(b)). This information is also included on the enclosed diskette.

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¹ "On January 1, 2003, Bayer Corporation was reorganized. The business, assets and operations of the unincorporated division of Bayer Corporation known as Bayer Pharmaceuticals became a stand alone business operated through Bayer Pharmaceuticals Corporation, a Delaware corporation, a newly formed subsidiary of Bayer Corporation. The business, assets and operations of the unincorporated division of Bayer Corporation known as Bayer Biological Products became a stand alone business operated through Bayer HealthCare LLC, a Delaware limited liability company, a newly formed subsidiary of Bayer Corporation."

Page 2 April 28, 2005

An assumption document detailing the methodology employed by Bayer to calculate the Average Sale Price (Section III (D)(2)(c)) certified by a high managerial agent of Bayer Pharmaceuticals Corporation and the Biological Products Division of Bayer HealthCare, LLC.

The CIA was amended in July 2004 to provide that the "average sale price" will have the meaning of and will be calculated in accordance with the Average Sales Price as defined in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Under the MMA, for the purposes of the Medicare Average Sales Price calculation, "unit" is the product represented by the 11-digit NDC (and not the smallest unit of measure used by Medicaid). However, CMS has advised that, for clotting factor products that are sold by strength (e.g., Koate, Kogenate), ASP should be reported in units of "IUs," the same as used for Medicaid reporting. The ASP values herein are reported by units as defined in the MMA and interpreted by CMS and accordingly will, in most cases, differ from the values previously reported by Bayer in its ASP reports (which were based on units as defined by Medicaid).

As previously advised, on October 1, 2004, Bayer transferred all responsibility for commercialization of a number of its primary care pharmaceutical products to Schering Plough (Transferred Products). A list of these products is attached. Between October 1 and December 31, 2004, these Transferred Products were sold under Bayer's NDCs and were reported in Bayer's 4Q2004 report. As a result of this transaction, as of January 1, 2005, Bayer no longer sells the Transferred Products. Therefore, beginning with 1Q2005, Bayer has no sales upon which to calculate a new ASP and these products will be removed from this and future reports.

Page 3 April 28, 2005

We wish to stress that this report of Average Sale Price arises from the above-referenced settlement. It is not intended to set reimbursement rates and is not a substitute for the reporting of Average Wholesale Price (AWP), Average Manufacturers Price (AMP) and/or Best Price (BP).

Please contact Mr. Jeffrey Greenman (203-812-2037) or me (203-812-6081) if you have any questions.

Very truly yours,

kf

Enclosures

Paul R. Berry

cc: Attached List

CERTIFICATION

The undersigned, a high managerial agent of Bayer Pharmaceuticals Corporation and the Biological Products Division of Bayer HealthCare, LLC, hereby certifies that the attached average sale price information has been communicated to First DataBank (an operating unit of The Hearst Corporation) and to the State Medicaid programs listed on the attached and that it has been calculated in accordance with the requirements of the Medicare Prescription Drug, Improvement, and Modernization Act of 2004, as they may be refined by the Secretary of the Department of Health and Human Services through regulations or written directives. I further acknowledge that the average sale prices so reported will be filed with the State Medicaid programs identified below.

State Medicaid Programs:

Per attached list.

Jeffrey M. Greenman

Vice President and Compliance Officer

16 18 100 1

Date

CONFIDENTIAL

Pharmacy Director Alabama Medicaid Agency 501 Dexter Avenue Montgomery, Alabama 36104

Paul Pontrelli, Pharm. D California Dept of Health Services Medi-Cal Policy Division 1501 Capitol Ave, Suite 71.3041 Sacramento, CA 95899-7413

Pharmacy Director EDS 248 Chapman Rd. Suite 200, Bristol Building Newark, Delaware 19702

Pharmacy Director Department of Human Services P.O. Box 339 Honolulu, Hawaii 96809-0339

Pharmacy Director Department of Human Services Hoover State Office Building Division of Medical Services Des Moines, Iowa 50319

M.J.Terrebonne Medicaid Director PO Box 91030 Baton Rouge, Louisiana 70821

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Pharmacy Director

Sont To Medicaid Services Bureau

Dept. of Public Health
or PO. P.O. Box 202951, 1400 Broadway
Helena, Montana 59620

Bayer



Jeffrey M. Greenman, Esq. Vice President and Compliance Officer

October 27, 2006

Robert J. Hawley, Esq. The Hearst Corporation Office of General Counsel 959 Eighth Avenue New York, New York 10019

Re: Report of Average Sale Price – 3rd Quarter 2006

In conformance with the State Settlement Agreement entered into August 6, 2001 among Bayer Corporation¹ ("Bayer") and the forty-five states, plus the District of Columbia, specified on attachment hereto, Bayer submits the following:

- Report of Average Sale Price for the third quarter 2006.
 This information is also included on the enclosed diskette.
- An assumptions document detailing the methodology employed by Bayer to calculate the Average Sale Price; and
- A certification by a high managerial agent of Bayer Pharmaceuticals Corporation and the Biological Products Division of Bayer HealthCare, LLC.

We wish to stress that this report of Average Sale Price arises from the above-referenced settlement. It is not intended to set reimbursement rates and is not a substitute for the reporting of Average Wholesale Price (AWP), Average Manufacturers Price (AMP) and/or Best Price (BP).

Bayer HealthCare LLC 400 Morgan Lane West Haven, CT 06516

Phone: 203 812-2037 Fax: 203 812-5492 jeffrey.greenman.b@bayer.com

¹ "On January 1, 2003, Bayer Corporation was reorganized. The business, assets and operations of the unincorporated division of Bayer Corporation known as Bayer Pharmaceuticals became a stand alone business operated through Bayer Pharmaceuticals Corporation, a Delaware corporation, a newly formed subsidiary of Bayer Corporation. The business, assets and operations of the unincorporated division of Bayer Corporation known as Bayer Biological Products became a stand alone business operated through Bayer HealthCare LLC, a Delaware limited liability company, a newly formed subsidiary of Bayer Corporation."

Page 2

Bayer's obligation to report Average Sales Price pursuant to the terms of the Corporate Integrity Agreement entered into January 23, 2001 between Bayer and the Office of Inspector General of the United States Department of Health and Human Services ("OIG") expired on January 23, 2006. A copy of this transmittal letter is being provided to the OIG for informational purposes.

In addition, we wish to note that the period covered by Bayer's obligation to report Average Sales Price pursuant to the State Settlement Agreement expired August 6, 2006. For ease of reporting, however, Bayer provided Average Sales Price for the full Q306.

Please contact me if you have any questions.

Very truly yours,

7.00

JMG/kf Enclosures

cc: Nicole C. Hall, Esq. (OIG)

Attached List

CERTIFICATION

The undersigned, a high managerial agent of Bayer Pharmaceuticals Corporation and the Biological Products Division of Bayer HealthCare, LLC, hereby certifies that the attached average sale price information has been communicated to First DataBank (an operating unit of The Hearst Corporation) and to the State Medicaid programs listed on the attached and that it has been calculated in accordance with the requirements of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, as they may be refined by the Secretary of the Department of Health and Human Services through regulations or written directives. I further acknowledge that the average sale prices so reported will be filed with the State Medicaid programs identified below.

State Medicaid Programs:

Per attached list.

Jeffrey M. Greenman

Vice President and Compliance Officer

Date Date

Pharmacy Director
Alabama Medicaid Agency501 Dexter AvenueMontgomery, Alabama 36104</ti>

Paul Pontrelli, Pharm. D California Dept of Health Services Medi-Cal Policy Division 1501 Capitol Ave, Suite 71.3041 Sacramento, CA 95899-7413

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